

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OTSUKA PHARMACEUTICAL CO., LTD.
AND H. LUNDBECK A/S,

Plaintiffs,

v.

UNICHEM LABORATORIES LTD.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. (“Otsuka”) and H. Lundbeck A/S (“Lundbeck”) (collectively, “Plaintiffs”), by way of Complaint against Defendant Unichem Laboratories Ltd. (“Unichem”), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Reissue Patent No. RE48,059 (“the RE’059 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Unichem’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to engage in the commercial manufacture, use or sale of its generic pharmaceutical products before the expiration of the RE’059 patent.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the RE'059 patent.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Unichem is a corporation organized under the laws of India and its principal place of business is located at Centre of Excellence, Plot No. 12 to 14, Pilerne Industrial Estate, Pilerne, Bardez, Goa 403 511, India.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Unichem. Upon information and belief, Unichem is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Unichem directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Unichem purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Unichem's generic products.

8. Upon information and belief, Unichem admits that "[i]n the USA, Unichem markets a growing list of USFDA approved products" and it "has several USFDA approved Abbreviated New Drug Applications (ANDAs) and continues to file new Drug Master Files (DMFs) and ANDAs for USFDA approval and launch in the U.S. market." <https://www.unichemlabs.com/americas.php> (accessed Sept. 24, 2020).

9. Upon information and belief, Unichem admits it has "50+ ANDAs" and "25+

approvals in US[.]” and “[t]he key objective of generic research programs at [Unichem] is to file top quality ANDAs and dossiers in regulated markets like the US[.]” <https://www.unichemlabs.com/research-centre-goa.php> (accessed Sept. 24, 2020)

10. Upon information and belief, Unichem is the holder of FDA Drug Master File No. 33437 for brexpiprazole.

11. Unichem’s ANDA filing regarding the RE’059 patent relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Unichem’s intent to market and sell Unichem’s generic products in this judicial district.

12. Unichem has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Unichem intends to direct sales of its generic drugs in this judicial district, among other places, once Unichem receives the requested FDA approval to market its generic products. Upon information and belief, Unichem will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

13. Upon information and belief, Unichem has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213710.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Unichem is incorporated in India and may be sued in any judicial district.

FACTUAL BACKGROUND

The NDA

15. Otsuka is the holder of New Drug Application (“NDA”) No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms (“REXULTI® Tablets”).

16. The FDA approved NDA No. 205422 on July 10, 2015.

17. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patent In Suit

18. The United States Patent and Trademark Office (“the PTO”) issued U.S. Patent No. 7,888,362 (“the ’362 patent”) on February 15, 2011, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.”

19. The PTO reissued the ’362 patent as the RE’059 patent on June 23, 2020. A true and correct copy of the RE’059 patent is attached hereto as Exhibit A.

20. As the reissue of the ’362 patent, Otsuka is the owner of the RE’059 patent through assignment as recorded by the PTO for the ’362 patent at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

21. Pursuant to 35 U.S.C. § 251, the RE’059 patent issued for the unexpired term of the ’362 patent, which would have expired on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed 317 days of patent term adjustment granted to the ’362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

22. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, requesting an extension under 35 U.S.C. § 156(c) of 986 days for the '362 patent. After the RE'059 patent issued, Otsuka filed a Petition Under 37 C.F.R. § 1.182 to Move Patent Term Extension Application from U.S. Patent No. 7,888,362 to RE 48,059. Accordingly, the RE'059 patent will expire on December 23, 2028, based on the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

23. The RE'059 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

24. Upon information and belief, Unichem filed ANDA No. 213710 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.5, 1, 2, 3 and 4 mg ("Unichem's generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

25. Otsuka and Lundbeck received a letter sent by Unichem, dated September 5, 2019, purporting to be a "Notice of Certification" for ANDA No. 213710 ("Unichem's September 5, 2019, First Notice Letter"), pursuant to §§ 505(j)(2)(B)(i), (ii), (iii) and (iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Unichem's September 5, 2019, First Notice Letter notified Plaintiffs that Unichem had filed ANDA No. 213710, seeking approval to engage in the commercial manufacture, use or sale of Unichem's generic products before the expiration of the '362 patent and U.S. Patent Nos. 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent") and 10,307,419 ("the '419 patent").

26. In response to Unichem's September 5, 2019, First Notice Letter, Plaintiffs filed a separate action in this Court against Unichem for patent infringement, which included counts of infringement of the '362, '840, '109, '637 and '419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Unichem Labs. Ltd.*, C.A. No. 19-1977-LPS.

27. On June 23, 2020, the PTO issued the RE'059 patent as a reissue of the '362 patent. Plaintiffs timely notified the FDA and the RE'059 patent was listed in the Orange Book for REXULTI®.

28. Upon information and belief, ANDA No. 213710 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the RE'059 patent are invalid, unenforceable and/or would not be infringed by Unichem's generic products.

29. Otsuka received a second notice letter sent by Unichem, dated August 11, 2020, purporting to be a "Notice of Certification" for ANDA No. 213710 ("Unichem's August 11, 2020, Second Notice Letter") pursuant to §§ 505(j)(2)(B)(i), (ii), (iii) and (iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Unichem's August 11, 2020, Second Notice Letter notified Otsuka that Unichem had filed ANDA No. 213710, seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Unichem's generic products before the expiration of the RE'059 patent.

30. Plaintiffs commenced this action within 45 days of receiving Unichem's August 11, 2020, Second Notice Letter.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

31. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

32. Upon information and belief, Unichem filed ANDA No. 213710 seeking approval to manufacture, use, import, offer to sell and/or sell Unichem's generic products in the United States before the expiration of the RE'059 patent.

33. Upon information and belief, Unichem filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the RE'059 patent are invalid, unenforceable and/or not infringed.

34. Upon information and belief, in its ANDA No. 213710, Unichem has represented to the FDA that Unichem's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

35. Unichem has actual knowledge of Otsuka's RE'059 patent, as evidenced by Unichem's August 11, 2020, Second Notice Letter.

36. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Unichem has infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213710, seeking approval to commercially manufacture, use, import, offer to sell or sell Unichem's generic products before the expiration date of the RE'059 patent.

37. Upon information and belief, if ANDA No. 213710 is approved, Unichem intends to and will offer to sell, sell and/or import in the United States Unichem's generic products.

38. Upon information and belief, if ANDA No. 213710 is approved, Unichem will infringe one or more claims of the RE'059 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Unichem's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any

FDA approval of ANDA No. 213710 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

39. Upon information and belief, Unichem's actions relating to Unichem's ANDA No. 213710 complained of herein were done by and for the benefit of Unichem.

40. Plaintiffs will be irreparably harmed by Unichem's infringing activities unless this Court enjoins those activities.

41. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Unichem has infringed at least one claim of each of the RE'059 patent through Unichem's submission of ANDA No. 213710 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Unichem's generic products in the United States before the expiration of the RE'059 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Unichem's making, using, offering to sell, selling or importing of Unichem's generic products before the expiration of the RE'059 patent will infringe, actively induce infringement and/or contribute to the infringement of the RE'059 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Unichem's generic products shall be no earlier than the expiration date of the RE'059 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Unichem and all persons acting in concert with Unichem from commercially manufacturing, using, offering for sale or selling Unichem's generic products within the United States, or importing Unichem's generic

products into the United States, until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Unichem and all persons acting in concert with Unichem from seeking, obtaining or maintaining approval of the ANDA until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

Of Counsel:

James B. Monroe
Denise Main
Erin M. Sommers
C. Collette Corser
Tyler B. Latcham
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

*Attorneys for Plaintiffs Otsuka
Pharmaceutical Co., Ltd. and H. Lundbeck
A/S*

Dated: September 25, 2020